UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF MICHIGAN

IN RE PRANDIN DIRECT PURCHASER ANTITRUST LITIGATION	C.A. No. 2:10-cv-12141-AC-DAS Judge Avern Cohn
THIS DOCUMENT RELATES TO: ALL ACTIONS	Magistrate Judge Donald A. Scheer **Jury Trial Demanded**

CONSOLIDATED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

PAGE

Plaintiffs American Sales Company, Inc. and Rochester Drug Co-Operative, Inc. ("Plaintiffs"), individually and on behalf of all others similarly situated, for their complaint against defendants Novo Nordisk A/S and Novo Nordisk, Inc. (collectively "Novo Nordisk" or "Defendants"), upon knowledge as to themselves and their own acts, and upon information and belief as to all other matters, allege as follows:

I. NATURE OF THE ACTION

1. Plaintiffs bring this action on behalf of themselves and a class of direct purchasers of Prandin. Prandin is the brand name for the prescription drug repaglinide, which is used to treat Type 2 (non-insulin dependent) diabetes mellitus ("NIDDM"), either alone ("monotherapy") or in combination with other anti-diabetes medicines ("combination therapy"), as an adjunct to a diet and exercise program.

2. Prandin is part of a class of diabetes drugs called meglitinides. Prandin helps the pancreas make more insulin, which helps to lower blood sugar. It is designed to lower blood sugar levels following a meal. Prandin sales in the United States are approximately $150 million per year.

3. On December 22, 1997, Novo Nordisk Inc. received approval from the U.S. Food and Drug Administration ("FDA") to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets (NDA No. 020741). The FDA has approved three uses of repaglinide to treat NIDDM: (1) repaglinide by itself, known as monotherapy; (2) repaglinide in combination with thiazolidinediones (TZDs); and (3) repaglinide in combination with metformin.

4. In the FDA publication Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the "Orange Book"), Novo Nordisk listed U.S. Pat.

No. RE37,035 ("the compound patent"), which covered the repaglinide compound and expired on March 14, 2009.

5. Novo Nordisk also listed U.S. Pat. No. 6,677,358 ("the '358 patent"), entitled "NIDDM REGIMEN," which issued on January 13, 2004 and expires June 12, 2018.

6. The '358 patent claims, among other things, the method for treating NIDDM by administering repaglinide in combination with metformin (claim 4). The '358 patent relates to the repaglinide-metformin combination only and does not relate to the other two approved uses of Prandin, *i.e.*, monotherapy and in combination with TZDs.

7. Caraco Pharmaceutical Laboratories, Inc. ("Caraco"), a generic drug manufacturer, has sought to market a less expensive, generic version of Prandin. On February 9, 2005, Caraco filed with the FDA an Abbreviated New Drug Application ("ANDA") for approval to market 0.5 mg, 1 mg, and 2 mg repaglinide tablets in the United States. In connection with its ANDA, Caraco did not challenge the compound patent that Defendants listed in the Orange Book, but did certify that the '358 patent was invalid and/or not infringed, and provided notice of this certification – known as a "Paragraph IV certification" – to Novo Nordisk.

8. The FDA tentatively approved Caraco's ANDA for generic repaglinide in August 2007, but did not finally approve the ANDA because the compound patent did not expire until March 14, 2009, and because in June 2005, Novo Nordisk sued to block Caraco's generic drug by asserting infringement of the '358 patent. *Novo Nordisk A/S, et al. v. Caraco Pharmaceutical Laboratories, Inc.*, No. 2:05-cv-40188 (E.D. Mich.). The patent infringement action remains pending.

9. In connection with the patent infringement action, Caraco has asserted, inter alia, that the '358 patent is unenforceable due to Novo Nordisk's inequitable conduct and patent misuse. Caraco also has asserted that, because it does not seek to market generic repaglinide for any indication or method of use covered by the '358 patent, its marketing of generic repaglinide would not directly or indirectly infringe any claim of the '358 patent.

10. Caraco's noninfringement argument came about as follows. In April 2008, at the suggestion of FDA, Caraco amended its ANDA to include a "split certification," by which it maintained its Paragraph IV certification challenging the non-method claims of the '358 patent (claims 1-3 and 5), but included a "section viii statement" specifying that it did not seek approval to market generic repaglinide for the metformin-combination method of use (claim 4). On December 4, 2008, FDA ruled, in response to a Citizen Petition filed by Novo Nordisk, that Caraco's section viii statement properly "carved out" (*i.e.*, omitted mention of information concerning indications, uses, or conditions of use covered by) the '358 patent's method of use claim. FDA ruled as follows:

> We have reviewed the petitions and other relevant information available to us. For the reasons stated above, we deny the Novo Nordisk Petition requesting that FDA refrain from approving any ANDAs for a repaglinide product that omits information on metformin combination therapy.

11. As a result of FDA's ruling and anticipated final approval of Caraco's ANDA with appropriate labeling "carve outs," on December 18, 2008, Novo Nordisk filed petitions with the FDA seeking reconsideration of the December 4, 2008 decision, and a stay of FDA's approval of Caraco's ANDA.

12. Specifically, Novo Nordisk requested that "FDA stay its Citizen Petition Response, and refrain from taking any regulatory action consistent with the Citizen Petition Response, including but not limited to, granting any tentative or final approval based upon the analysis contained in the Citizen Petition Response (*i.e.*, granting any approvals for generic repaglinide that omit information on metformin combination therapy)." Without such a stay, Novo Nordisk complained, as of the expiration of the compound patent on March 14, 2009, "FDA could approve Caraco's [ANDA], and Caraco could commence commercial marketing of generic repaglinide using FDA-approved labeling[.]" That turn of events would "irreparably harm" Novo Nordisk because "generic substitution of Caraco's drug will be widespread – causing immediate and significant loss of market share to Novo Nordisk," Novo Nordisk said.

13. Novo Nordisk made similar assertions when it asked the Court to issue a preliminary injunction ordering Caraco not to launch its generic repaglinide, which Novo Nordisk deemed necessary because Caraco "repeatedly [has] represented that they will launch their generic product in mid-March 2009, with or without an adjudication of the merits." Novo's Motion for Preliminary Injunction, at 1 (Feb. 25, 2009).

14. Based on FDA's ruling and its labeling "carve outs," Caraco filed a motion for summary judgment of noninfringement. In response to Caraco's noninfringement argument, the Court stated that "if FDA issues an approval of [Caraco's current ANDA], they will issue an approval on the label that does not, by its terms, induce infringement." Hearing Tr. of 3/27/09 at 47:3-5.

15. On May 6, 2009, faced with the imminent final approval and launch of Caraco's inexpensive generic repaglinide, Novo Nordisk submitted to the FDA a change in the "use code"

narrative for the ’358 patent reference in the Orange Book. Specifically, Novo Nordisk filed a use code narrative that expanded the description of the claim under the ’358 patent in the Orange Book far beyond the repaglinide-metformin combination that was actually claimed in the ‘358 patent. In fact, Novo Nordisk’s new use code narrative for the ’358 patent was so broad that it included all approved uses of repaglinide, including *two uses that were the subject of expired other patents and which therefore could not possibly be covered by the ’358 patent*.

16. As Novo Nordisk knew, the broadening of its use code narrative for the ’358 patent would prevent the FDA from approving Caraco’s ANDA because the FDA (a) does not evaluate the merits of use code submissions, but instead merely acts ministerially to publish them when submitted by drug companies; and (b) would not and could not approve Caraco’s ANDA in light of the new use code narrative, because there were no longer any approved uses that were outside of the new narrative’s improperly-broadened scope.

17. This is exactly what happened. Solely as a result of Novo Nordisk’s anticompetitive tactic in changing the “use code” narrative, final ANDA approval to Caraco’s generic repaglinide with labeling “carve-outs” has been blocked. On June 16, 2009, the FDA stated:

> Because FDA lacks expertise in assessing patents, the Agency determines which labeling corresponds to a submitted patent (and thus which labeling may be available to carve out) by relying on the use code for that patent submitted by the sponsor. Because the use code for the ’358 patent has changed since our issuance of the Citizen Petition Response and because our analysis and conclusions regarding labeling carveouts in that Citizen Petition Response were based on the previous use code, the factual predicate on which our previous response was based no longer applies.

18. Novo Nordisk's attorneys have admitted in open court that Novo Nordisk's change in the "use code" narrative for the '358 patent was "a response to the section viii ruling – in response to the citizen petition in December '08 from FDA."

19. As a result of this anticompetitive and exclusionary conduct relating to the use code narrative for the '358 patent, Novo Nordisk improperly maintained and extended its monopoly power over repaglinide. It kept repaglinide prices artificially high, lowered consumer welfare, and harmed direct purchasers, who were overcharged because cheaper A-rated generic repaglinide was blocked from the market as a direct and proximate result of Novo Nordisk's misconduct.

20. On September 24, 2009, the Court entered an injunction requiring Novo Nordisk to return the use code to its original form. This Court recognized that the '358 patent's method claim only covers use of repaglinide in combination with metformin to lower blood glucose. *See Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 656 F. Supp.2d 729 (E.D. Mich. 2009). However, the United States Court of Appeals for the Federal Circuit initially stayed and then vacated the injunction on the ground that, while the relevant provision of the Hatch-Waxman Act (21 U.S.C. § 355(j)(5)(C)(ii)(I)) authorized a counterclaim to correct or delete an erroneous patent number or expiration date, it did not authorize a counterclaim to change a use code narrative. *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, No. 2010-1001, 601 F.3d 1359, 1366 (Fed. Cir. 2010) ("[T]he terms of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative.").

21. Novo Nordisk's actions regarding the use code narrative for the '358 patent are not the only anticompetitive misconduct in which it has engaged in connection with Prandin. As

part of its overarching scheme to monopolize, Novo Nordisk obtained the '358 patent through intentional fraud on the Patent and Trademark Office ("PTO") by withholding material information and making material false statements with the intention to deceive the PTO into issuing the '358 patent. Novo Nordisk committed further anticompetitive conduct by listing the fraudulently-obtained '358 patent in the FDA "Orange Book," and by thereafter filing sham lawsuits based on the '358 patent.

22. Thus, Novo Nordisk has maintained an unlawful monopoly in the market for repaglinide (which, for the reasons described below is composed of, and limited to, Prandin and A-rated generic versions of repaglinide) by blocking generic versions of Prandin from the market with an improper and anticompetitive "use code" narrative, an improper and anticompetitive Orange Book filing, fraud on the PTO, and sham litigation. Were it not for Novo Nordisk's unlawful conduct, suppliers of generic Prandin (including but not limited to Caraco, Mylan Pharmaceuticals, Inc., and Paddock Laboratories, Inc.) would have obtained FDA approval to market A-rated versions of repaglinide as early as March 15, 2009, thereby causing prices of repaglinide to decline significantly.

23. Defendants' continuing anticompetitive acts have deprived direct purchasers of a less-expensive A-rated generic repaglinide, and thereby allowed Defendants to force direct purchasers to purchase more-expensive branded Prandin to satisfy their requirements for repaglinide, thereby causing Plaintiffs and all direct purchasers of Prandin to pay overcharges on their purchases of repaglinide.

II. JURISDICTION AND VENUE

24. Plaintiffs bring this action alleging violation of § 2 of the Sherman Act, 15 U.S.C. § 2, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15, as a result of exclusionary, monopolistic and unlawful restraints on trade that have harmed and continue to harm Plaintiffs and the Class. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a).

25. Venue is proper within this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), because Defendants are found or transact business within this District and/or because the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

III. PARTIES

26. Plaintiff American Sales Company, Inc. ("ASC") is a Delaware corporation with its principal place of business in Lancaster, Erie County, New York. ASC purchases health products, including prescription drugs, for retail stores owned and operated by affiliated companies. During the relevant period, ASC purchased Prandin from Cardinal Health, Inc. ("Cardinal"), a pharmaceutical wholesaler which during the relevant period purchased Prandin directly from Defendants. Cardinal was injured as a result of Defendants' misconduct. Cardinal resold Prandin to ASC and has assigned its claims arising out of those purchases to ASC. ASC brings this action on its own behalf as the assignee of Cardinal.

27. Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with a principal place of business located at 50 Jet View Drive, Rochester, New York 14624. During the relevant

period, RDC purchased Prandin directly from Defendants and was injured as a result of Defendants' misconduct.

28. Defendant Novo Nordisk A/S is a Danish corporation having a place of business at Novo Alle, DK-2880 Bagsvaerd, Denmark. Novo Nordisk has become one of the world's largest sellers of prescription drugs for diabetes. Novo Nordisk has production facilities in six countries, with affiliates or offices in 80 countries. Novo Nordisk employs approximately 26,000 people globally and markets its products in 179 countries, including the United States. Novo Nordisk A/S is the owner by assignment of United States Patent No. 6,677,358 ("the '358 patent").

29. Defendant Novo Nordisk, Inc. is a Delaware corporation having a principal place of business at 100 College Road West, Princeton, New Jersey. Pursuant to NDA No. 020741, Novo Nordisk Inc. received approval from the FDA to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets in the United States.

IV. INTERSTATE COMMERCE

30. During all or part of the Class Period (defined below), Defendants manufactured and sold substantial amounts of Prandin in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

31. At all material times, Prandin that was manufactured and sold by Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

32. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous

and uninterrupted flow of commerce across state and national lines in connection with the sale of Prandin.

33. In furtherance of its efforts willfully to obtain and/or maintain monopoly power over Prandin and it's A-rated generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

34. Defendants' efforts to willfully maintain monopoly power over Prandin and its generic equivalents, as alleged herein, have substantially affected interstate and foreign commerce.

V. CLASS ALLEGATIONS

35. Plaintiffs bring this class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of a class (the "Class") defined as follows:

> All persons and entities in the United States who purchased Prandin directly from Defendants from March 15, 2009 until the date the Court certifies the Class. Excluded from the Class are Defendants and their parents, employees, subsidiaries, and affiliates, and federal governmental entities.

36. The Class is so numerous that joinder of all members is impracticable.

37. There are questions of law or fact common to the Class, including:

a. whether Novo Nordisk willfully maintained monopoly power over Prandin and its A-rated generic equivalents;

b. whether Novo Nordisk wrongfully and improperly filed a new and inaccurate use code narrative with FDA for the purpose of preventing or delaying competition;

c. whether the ’358 patent was obtained through fraud and/or inequitable conduct;

d. whether Novo Nordisk’s lawsuits asserting infringement of the ’358 patent are objectively baseless;

e. whether Novo Nordisk filed such lawsuits for the purpose of preventing or delaying competition; and

f. whether, and to what extent, Novo Nordisk’s conduct caused direct purchasers of Prandin to be overcharged and therefore injured.

38. These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

39. Plaintiffs’ claims are typical of the claims of the Class because all Class members suffered antitrust injury in the same way as a result of Defendants’ wrongdoing, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

40. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel experienced in class action and pharmaceutical antitrust litigation, and have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

41. A class action is superior to any other available method for the fair and efficient adjudication of this controversy. Plaintiffs know of no difficulty that will be encountered in the management of the claims that would preclude class certification.

VI. BACKGROUND

A. Brand Name Drugs Versus Generic Drugs

42. The brand name prescription drugs industry is one of the most profitable industries in the United States. Over $300 billion was spent on prescription drugs in the United States in 2009, with $226 billion spent on brand name drugs. The cost of prescription drugs has been rising at a rate of 14% to 18% per year. From 2004 to 2007, brand name drug prices increased by an average of 21%, while generic drug prices decreased by an average of 12.8% during the same period.

43. Securing the availability of generic drugs is one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which must be approved by FDA, by law have the same active chemical composition and provide the same therapeutic effects as the brand name drugs to which they correspond.

44. FDA will assign an "A" rating to generic drugs that are bioequivalent to the reference or brand name drugs. To be deemed a therapeutic equivalent, and receive an "A" rating from FDA, the generic drug must also contain the same active ingredient(s), dosage form, route of administration, and strength. According to FDA, a bioequivalent drug rated "A" may be substituted by pharmacists for the branded drug.

45. Once the safety and effectiveness of a new prescription drug is approved by FDA, the drug may be used in the United States only under the direction and care of a physician who writes a prescription, specifying the drug by name, which must be purchased from a licensed pharmacist. The pharmacist, in turn, must fill the prescription with the drug brand specified by the physician, unless an A-rated generic version approved by FDA is available.

46. If a generic version exists and the physician has not specifically indicated to the pharmacist to dispense the branded drug then: (i) in many states, the pharmacist by law must substitute the generic drug; (ii) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug, and (iii) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the option of purchasing the branded drug or the A-rated generic drug at a lower price.

47. Once a physician writes a prescription for a brand name drug, such as Prandin, that prescription defines and limits the market to the drug name or its A-rated generic equivalents. Only drugs that are A-rated by FDA may be substituted by a pharmacist for a physician's prescription for the brand name drug.

48. Generic drugs are priced substantially below the brand name drugs to which they are bioequivalent. A recent study by the Generic Pharmaceutical Association based on an independent analysis of data from IMS showed that the use of generic drugs has saved consumers, patients, and healthcare providers $734 billion from 1998 through 2008, with approximately $121 billion in savings in 2008 alone.

49. The Federal Trade Commission ("FTC") estimates that the first generic manufacturer to enter the market for a given drug product typically charges between 70% and 80% of the price of the corresponding brand name drug during periods of generic marketing exclusivity. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

50. A brand name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, as much as 90% in just the first year of generic sales.

B. Federal Scheme for Approval of Branded Drugs

51. The Federal Food, Drug, and Cosmetic Act ("the FFDCA"), 21 U.S.C. § 301, *et seq*. regulates the manufacture and distribution of drugs and medical devices in the United States. Under the FFDCA, approval by the FDA (the governmental body charged with the regulation of the pharmaceutical industry) is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 335(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 335(b) of the FFDCA, demonstrating that the drug is safe and effective for its intended use.

52. New drugs that are approved for sale in the United States by the FDA are often covered by patents, which provide the patent owner with the ability to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) that new drug in the United States for the duration of the patent, plus any extension of exclusivity granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("Hatch-Waxman Act").

53. Pursuant to 21 U.S.C. § 335(b), the pioneer drug manufacturer must list in its NDA those patents that claim the drug for which FDA approval is being sought or that claim a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. If a particular patent does not meet this test with respect to the NDA, the patent cannot properly be listed with

FDA. Once the NDA is approved by the FDA, any such patents are listed in a publication known as the *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book."

54. Federal regulations impose strict limitations on the types of the patents that an NDA holder can submit to the FDA for listing in the Orange Book. *See generally* 21 C.F.R. § 314.53. One such limitation is imposed by 21 C.F.R. § 314.53(b), which explicitly prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

55. Despite FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has regrettably become common for brand name pharmaceutical companies to list in the Orange Book any and every patent they can obtain, in order to force generic manufacturers to file what, as described below, is commonly known as a "Paragraph IV Certification."

56. FDA does not police the listing of patents or other material in the FDA Orange Book. FDA employs no adjudicatory or other process to determine whether a patent or other material submitted by an NDA holder qualifies for listing in the Orange Book. FDA has stated that it lacks the resources and expertise to review the patents submitted in connection with NDAs. *See* 59 Fed. Reg. 50338, 50343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information").

57. The FDA relies entirely on the NDA holder to list its patent accurately, and its role in the patent listing process is purely ministerial.

C. Approval of Generic Drugs

58. Congress enacted the Hatch-Waxman Act in 1984. The Hatch-Waxman Act was principally designed to streamline the process by which generic drugs are brought to market. The Hatch-Waxman Act simplified the regulatory hurdles faced by prospective generic drug manufacturers by eliminating the need for such manufacturers to file lengthy and costly NDAs. Under the Hatch-Waxman Act, a generic drug manufacturer may seek expedited FDA approval to market a generic version of a brand name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j). An ANDA relies on the safety and efficacy data already filed with FDA by the manufacturer of the corresponding brand name drug.

59. Under the Hatch-Waxman Act, a generic drug manufacturer's ANDA must contain a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii) addressing the patents, if any, listed in the Orange Book as applying to the brand name or pioneer drug. Four types of certifications are available:

I. The brand name manufacturer has not filed patent information with FDA (a "Paragraph I Certification");

II. The patent or patents listed in the Orange Book have expired (a "Paragraph II Certification");

III. The patent or patents listed in the Orange Book will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration (a "Paragraph III Certification"); or

IV. The patent or patents listed in the Orange Book are invalid or not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii).

60. If a generic manufacturer files a Paragraph IV Certification, seeking to market the generic drug before patent expiration and asserting that any listed patent is invalid or will not be infringed, the brand name manufacturer has the opportunity to delay the generic manufacturer's receipt of final FDA approval, and thus its ability to come to market. This is because a generic manufacturer filing a Paragraph IV Certification must promptly give notice of this fact to both the NDA owner and the owner of the patent(s) at issue, and this certification may constitute a "technical act of infringement" under the Hatch-Waxman Act.

61. The filing of a Paragraph IV Certification thus creates jurisdiction in the federal courts to entertain a patent infringement action, and the NDA holder has 45 days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If such a suit is initiated, FDA's approval of the ANDA is automatically stayed for up to 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

62. Because of this 30-month stay of ANDA approval, the mere filing of an infringement action in response to a Paragraph IV Certification, regardless of the action's underlying merit, gives the brand name company the equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor, without requiring the brand company to establish likelihood of success on the merits, irreparable harm, that the balance of hardships tips in its favor, or that the public good is served by the blocking of entry.

63. As a practical matter, the brand name company obtains an injunction simply by filing a complaint, even a complaint with little or no merit, as it automatically protects its monopoly for up to two-and-one-half years while the infringement action winds its way through the court system. Moreover, the brand name company has an incentive to stall the progress of the litigation. There are no disgorgement provisions for profits earned during the 30-month period of exclusivity if a court eventually determines that the suit was without merit.

64. An improper Orange Book listing has additional anticompetitive effects because the first generic company to file an ANDA with a Paragraph IV Certification is, upon FDA approval, granted a 180-day period of marketing exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). Absent an improper Orange Book listing, no Paragraph IV Certification would be required and, thus, no generic company would receive any 180-day exclusivity; rather, multiple generic competitors would enter the market simultaneously, resulting in prices even lower than one would find during the 180-day exclusivity period when only one generic manufacturer is permitted to market its A-rated product.

65. Defendants were at all times fully familiar with the ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Amendments.

D. "Section viii Statements" That "Carve Out" Methods of Use

66. FDA regulations require NDA holders like Novo Nordisk to submit "patent information" to FDA "for each patent that claims the drug or a method of using the drug that is the subject of the new drug application … and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent

engaged in the manufacture, use, or sale of the drug product." 21 C.F.R. § 314.53(b); *see also* 21 U.S.C. § 355 (c)(2). This patent information is listed in the Orange Book, one purpose of which is to provide notice to ANDA applicants of those patents an NDA holder represents cover the listed product.

67. The FTC was involved in the discussions leading to the current iteration of section 314.53. It provided a detailed study of generic drug entry prior to patent expiration, and previously asked FDA to clarify its patent listing rules via Citizen Petition. *See, e.g.*, Citizen Petition, O1P-0248 (May 16, 2001). As FTC explained: "The FDA has proposed to clear away unnecessary roadblocks to the approval of generic drug products. The FDA's important action addressing the competitive problems existing in the approval process for generic drugs, if promulgated and upheld, will [be] an effective way to bring the economic benefits of generic drugs to consumers more quickly. The Commission urged the FDA, however, to make the proposed reforms even more effective by tightening its patent listing requirements." FTC Comments, Dkt. No. 02N-0417 (Dec. 23, 2002).

68. The NDA holder's obligation to submit patent information for method claims includes "use codes" and specific descriptions of the protected methods of use. 21 C.F.R. § 314.53(b)(1). "Use codes" are listed in the Orange Book and are intended to alert ANDA applicants to the existence of a patent that claims an approved use. *Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of [ANDAs] Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed, Final Rule*, 68 Fed. Reg. 36676, 36683 (June 18, 2003). "Use code

narratives" are written descriptions, provided by an NDA holder, of the approved method of use claimed by a patent.

69. Although it does not monitor or adjudicate the propriety of submitted use code narratives, FDA expects a high degree of specificity in these use codes so that ANDA applicants may, if they so elect, carve out the specific patented use from its label and seek approval solely for non-patented uses by submitting what is called a "section viii statement." *See* 21 U.S.C. § 355(j)(2)(A)(viii). As FDA put it: "To effectively implement the certification and section viii statement provisions set out in the statute, we must have adequate information concerning method-of-use patents." 68 Fed. Reg. at 36683. The FDA further stated: "[W]e believe that it is necessary that an NDA holder submit more specific information on the approved methods of use protected by a submitted patent. Only with this information can we determine what submission is required of the ANDA and 505(b)(2) applicants referencing the approved drug.". *Id.* Thus, under Section 314.53(b)(1),"[t]he applicant *shall separately identify each pending or approved method of use and related patent claim*" and "identify *with specificity* the section of the approved labeling that corresponds to the method of use claimed by the patent submitted" (emphasis added).

70. Indeed, when submitting a use code description to FDA, the NDA holder "must describe *each individual method of use* for which a patent is submitted for listing, and identify the corresponding language found in the labeling of the approved NDA that corresponds to that method of use." *Id*. at 36681 (emphasis added).

71. This listing must be "*accurate and detailed*" [*id*.]; the applicant must provide "a description of each approved method of use or indication and related patent claim of the patent

being submitted," along with "the specific section of the approved labeling of the drug product that corresponds to the method of use claimed by the patent" and a "*description of the patented method of use* as required for publication." 21 C.F.R. § 314.53(c)(2)(ii)(P).

72. Form FDA 3542, the form NDA holders must complete in connection with the use code requirements, also mandates that the NDA holder attest to the accuracy of a use code under penalty of perjury and specifically cautions that willfully and knowingly false statements are a criminal offense under 18 U.S.C. § 1001. *See* 68 Fed. Reg. at 36686. The instructions to Form 3542 make clear that generic companies must be able to rely on specific use codes to determine whether a section viii statement is appropriate: "The use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified in this section and contain adequate information to assist … ANDA applicants in determining whether a listed method of use patent claims a use for which the … ANDA applicant is not seeking approval." This instruction prevents the NDA holder from asserting a broad use code that would unnecessarily prevent ANDA applicants from seeking and obtaining approval for non-protected uses.

73. By placing these strict requirements on the NDA-holder, Section 314.53 and Form FDA 3542 implement a critical component of the Hatch-Waxman statutory scheme because they allow ANDA applicants to know precisely what methods they can carve out in a section viii statement. FDA does not construe patents, so it relies on the good-faith compliance of the NDA holder to provide an accurate and detailed use code narrative – *i.e.*, description of the patented method of use. *See* 68 Fed. Reg. at 36681 ("In determining whether an ANDA applicant can 'carve out' the method of use, rather than certify to the listed patent, *we will rely on*

the description of the approved use provided by the NDA holder or patent owner in the patent declaration and listed in the Orange Book.") (emphasis added). NDA holders may not ignore their good faith obligations to subvert the Hatch-Waxman statutory scheme. *See* J. Dohm, Comment, *Expanding the Scope of the Hatch-Waxman Act's Patent Carve-Out Exception to the Identical Drug Labeling Requirement: Closing the Patent Litigation Loophole,* 156 U. PA. L. REV. 151, 164 (2007) ("Instead of appropriately assigning the use code, pioneers may be motivated to assign an extremely broad use code to its method of use, thereby optimizing patent protection.").

VII. NOVO NORDISK'S ANTICOMPETITIVE CONDUCT

A. Novo Nordisk's Scheme to Block Generic Approval by Filing an Improper "Use Code" in the FDA Orange Book

1. FDA approved three uses of repaglinide to treat non-insulin dependent diabetes mellitus

74. On December 22, 1997, Novo Nordisk, Inc. received FDA approval to sell 0.5 mg, 1 mg, and 2 mg Prandin tablets (NDA No. 020741). The FDA has approved three uses of repaglinide to treat non-insulin dependent diabetes mellitus: (1) repaglinide by itself, known as monotherapy; (2) repaglinide in combination with thiazolidinediones (TZDs); and (3) repaglinide in combination with metformin.

75. Novo Nordisk listed three patents in the Orange Book in reference to Prandin: (1) U.S. Pat. No. RE37,035 ("the compound patent"), which covered the repaglinide compound and expired on March 14, 2009; (2) U.S. Patent No. 5,312,924, which covered the use of repaglinide in monotherapy to treat diabetes and expired in September 2006; and (3) U.S. Patent No. 6,677,358 ("the '358 patent"), entitled "NIDDM REGIMEN," which was issued on

January 13, 2004, and expires June 12, 2018. "NIDDM" is an abbreviation for non-insulin dependent diabetes mellitus.

76. The '358 patent claims a pharmaceutical composition which includes repaglinide, metformin, and a carrier (claim 1) in the form of a tablet (claim 2) or capsule (claim 3); the method for treating NIDDM by administering, to a patient in need of treatment, repaglinide in combination with metformin (claim 4); and a kit which includes repaglinide and metformin (claim 5). The '358 patent relates to the repaglinide-metformin combination *only* and does not relate to the other approved uses of Prandin.

77. On June 23, 2008, FDA approved Novo Nordisk Inc.'s application to market a drug that includes a combination of repaglinide and metformin, which Novo Nordisk markets under the brand name PrandiMet.

2. Caraco's ANDA

78. On February 9, 2005, Caraco filed ANDA No. 77-571 for approval to market 0.5 mg, 1 mg, and 2 mg generic repaglinide tablets in the United States. Under FDA regulations, the language of Caraco's proposed label had to match the Prandin label, including reference to all FDA-approved uses of repaglinide. *See* 21 U.S.C. § 355(j)(2)(A)(v). Caraco's ANDA included a Paragraph III certification with respect to the compound patent (*i.e.*, Caraco would not seek to market its generic repaglinide product until expiration of the compound patent on March 14, 2009) and a Paragraph IV certification with respect to all five claims of the '358 patent. Caraco was the first generic manufacturer to file a Paragraph IV ANDA challenging the '358 patent, making it eligible for a 180-day marketing exclusivity period upon final approval of its ANDA.

79. On April 26, 2005, Caraco sent a notice of its Paragraph IV certification to Novo Nordisk A/S and Novo Nordisk, Inc., pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

80. On June 9, 2005, within 45 days of the notice described above, Novo Nordisk filed a complaint against Caraco in the United States District Court for the Eastern District of Michigan, alleging that a generic label referencing the approved repaglinide-metformin use would actively induce infringement of the '358 patent. *Novo Nordisk A/S et al. v. Caraco Pharmaceutical Labs., Inc.*, No. 2:05-cv-40188 (E.D. Mich.). On September 14, 2005, Novo Nordisk filed an amended complaint adding Caraco's parent company (Sun Pharmaceutical Industries, Ltd.) as a defendant.

81. In August 2007, FDA granted tentative approval to Caraco's ANDA. The only circumstances precluding final approval were the compound patent (which was set to expire on March 14, 2009), and Novo Nordisk's patent infringement complaint.

3. Prandin label revised in 2007

82. In November 2007, as part of an ongoing reevaluation of the labeling of all oral antidiabetic drugs, FDA required Novo Nordisk to replace all separate indications with the following sentence: "Prandin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus."

4. Caraco's amended ANDA and section viii statement

83. In 2008, at the suggestion of FDA, Caraco amended its ANDA to include a "split certification," by which Caraco maintained its Paragraph IV certification for the non-method claims of the '358 patent (claims 1-3, 5), but submitted a section viii statement for the method claim (claim 4). Caraco's proposed label omitted all references to the patented metformin-

repaglinide combination, such that its generic repaglinide products would be labeled and marketed only for non-infringing, FDA-approved uses.

84. On June 9, 2008, Novo Nordisk challenged Caraco's proposed carve-out label in a citizen petition filed with FDA (FDA-2008-P-0343-0001). On December 4, 2008, FDA rejected Novo Nordisk's citizen petition and held that Caraco's section viii statement was proper in light of Novo Nordisk's use code description at the time – *i.e.*, "U-546: use of repaglinide in combination with metformin to lower blood glucose." This code made it clear that the '358 patent does not claim the other two approved repaglinide uses that would remain in Caraco's generic label. The FDA also rejected an alternative argument by Novo Nordisk that omitting the patented combination therapy from Caraco's generic label would compromise the safety and efficacy of the drug.

85. The FDA ruling meant that Caraco's repaglinide product would not be marketed for a use that infringes the '358 patent, which paved the way for: (1) mooting the patent infringement litigation; and (2) final marketing approval of Caraco's ANDA following the expiration of the compound patent on March 14, 2009.

5. Novo Nordisk filed an improper new "use code" with FDA in order to delay generic approval

86. On May 6, 2009, Novo Nordisk amended its use code narrative for Prandin in the Orange Book to read: "U-968: A method for improving glycemic control in adults with Type 2 diabetes mellitus." Novo Nordisk represented to FDA that the amendment was intended "to correspond with the change in labeling required by FDA in November 28, 2007." While FDA did institute a general change in oral diabetes drug labeling in November 2007 that required a corresponding change in the Prandin label, there is absolutely nothing in the statute or

regulations that required Novo Nordisk to change the use code narrative to track this change. FDA did not direct or request that Novo Nordisk make any change in the use code narrative. Novo Nordisk's attorneys admitted in open court that the FDA directive of 2007 "did not require" a change in the '358 patent's use code narrative.

87. Novo Nordisk changed the use code narrative solely to frustrate Caraco's ability to obtain final FDA approval of its ANDA. Contrary to the representation that Novo Nordisk made to FDA under penalty of perjury, Novo Nordisk's new use code (U-968) did not specifically or accurately describe the patented method of use found in claim 4 of the '358 patent – in fact, it did not describe that patented method at all. Instead, it vaguely suggested that the '358 patent is much broader in scope than it actually is, covering approved methods of use, such as monotherapy and combination therapy with thiazolidinediones (TZDs), other than the use claimed in the '358 patent (*i.e.*, use of repaglinide in combination with metformin).

88. Novo Nordisk's use code change was improperly submitted for listing in the Orange Book for the sole, anticompetitive purpose of preventing the FDA from finally approving Caraco's ANDA with labeling "carve outs" and preventing Caraco from obtaining a summary judgment of non-infringement.

89. The language of claim 4 of the '358 patent is expressly limited to the use of "repaglinide in combination with metformin" and cannot be construed to cover repaglinide monotherapy or combination therapy with TZDs. An approved label for a branded drug may cover both patented and unpatented uses. Nothing in the FDA regulations or FDA Form 3542 allows the patentee to derive Orange Book use code information from the portion of the label referring to unpatented uses. On the contrary, the applicable regulations and FDA Form 3542

are clear that the patentee is required to utilize those portions of the label that refer to the *patented* use. *See* 21 C.F.R. § 314.53(c)(2)(ii)(P)(2) (requiring NDA holder to identify "the specific section of the approved labeling for the drug product that corresponds to the method of use claimed by the patent submitted").

90. Other than in this instance, Novo Nordisk has always maintained that claim 4 of the'358 patent covers only the metformin-repaglinide combination – the only plausible reading of that claim. Indeed, Novo Nordisk continues to use its original '358 patent use code description (U-546) for its repaglinide-metformin combination tablet PrandiMet. Novo Nordisk's complaint for patent infringement against Caraco alleged that "[t]he '358 patent claims … a method for treating NIDDM by administering to a patient in need of treatment, repaglinide in combination with metformin (claim 4)." [Caraco Am. Compl. ¶ 10.] Novo Nordisk took the same position in other litigation involving the '358 patent. *See, e.g.*, Complaint ¶ 10, *Novo Nordisk et al. v. Mylan Pharmaceuticals Inc.*, U.S. District Court for the District of New Jersey Case No. 3-09-cv-02445. Similarly, in its Citizen Petition, Novo Nordisk represented that "the '358 patent contains 5 claims, one of which (claim 4) is directed to a method of treatment of NIDDM with a combination of repaglinide and metformin." Novo Nordisk Citizen Petition, FDA-2008-P-0343-0001, at 3 n.4 (Jun. 9, 2008).

91. For these reasons, Novo Nordisk's conduct in changing the use code narrative in the Orange Book was obviously anticompetitive. It did not constitute competition on the merits, had the effect of preventing or excluding generic repaglinide competition, and maintained, as was its intention, Novo Nordisk's monopoly power over repaglinide (Prandin and A-rated generic versions of Prandin). Indeed, Novo Nordisk acknowledged that the amended code

description was intended to counteract the FDA's December 2008 ruling and prevent FDA from approving ANDAs (like Caraco's) with section viii "carve outs" of the lone remaining approved and patented use of repaglinide (*i.e.*, the repaglinide-metformin combination to treat NIDDM.)

92. As a result of Novo Nordisk 's anticompetitive tactic, the FDA cannot accept a section viii statement carving out the patented repaglinide-metformin combination therapy from Caraco and therefore cannot grant final approval to Caraco's ANDA to market generic repaglinide for non-infringing uses.

93. Novo Nordisk was aware that FDA could not and would not construe the '358 patent in accepting Novo Nordisk's improper new use code narrative for filing, and that FDA would not grant final approval to Caraco's ANDA with such an improper use code narrative in place. On June 16, 2009, FDA denied Novo Nordisk's petition for reconsideration as moot because of the new use code, stating:

> FDA's role in listing patents in ministerial. FDA lists the patents submitted by the sponsor and publishes in the Orange Book the use codes that the sponsor provides. Sponsors must verify under penalty of perjury that the patent declaration represents "an accurate and complete submission of patent information" and attest that they are familiar with the requirements of 21 CFR 314.53 and that their submission complies with that regulation (21 CFR314.53(c)(2)(i)(Q)). FDA relies on the sponsors to craft an accurate and complete description of the relevant patent claims (to form the basis of the use code) and to identify the approved labeling that corresponds to those claims. Because FDA lacks expertise in assessing patents, the Agency determines which labeling corresponds to a submitted patent (and thus which labeling may be available to carve out) by relying on the use code submitted by the sponsor. Because the use code for the '358 patent has changed since our issuance of Citizen Petition Response and because our analysis and conclusions regarding labeling carveouts in that Citizen Petition Response were based on the previous use code, the factual predicate on which our previous response was based no longer applies. (Footnote omitted.)

94. As a result of Novo Nordisk's improper filing of a new "use code" narrative for Prandin, generic competition to Prandin has been blocked and delayed, and Plaintiffs and the Class have overpaid for their purchases of repaglinide. But for the improper "use code" narrative, Caraco would have received final ANDA approval shortly after the expiration of the compound patent, and would have then launched its generic repaglinide. Instead, Plaintiffs and the Class have been overcharged by paying more for their repaglinide requirements than they would and should have, as a direct and proximate result of Novo Nordisk's anticompetitive conduct.

6. The injunction requiring Novo Nordisk to revert to its original use code has been vacated

95. On September 25, 2009, the district court presiding over the patent infringement litigation entered an injunction requiring Novo Nordisk "to correct within twenty (20) days from the date of this Order and Injunction its inaccurate description of the '358 patent by submitting to FDA an amended Form FDA 3542 that reinstates its form U-546 listing for Prandin and describes claim 4 of the '358 patent in section 4.2b as covering the 'use of repaglinide in combination with metformin to lower blood glucose.'" *See Novo Nordisk A/S v. Caraco Pharmaceutical Labs., Ltd.*, 656 F. Supp.2d 729 (E.D. Mich. 2009).

96. On April 14, 2010, however, a split decision by the United States Court of Appeals for the Federal Circuit vacated the injunction on the ground that the provision of the Hatch-Waxman Act at issue relative to Caraco's counterclaim (*i.e.*, 21 U.S.C. § 355(j)(5)(C)(ii)(I)) could not be applied to use code narratives and could only be used to correct or delete an erroneous patent number or expiration date. *Novo Nordisk A/S v. Caraco Pharmaceutical Labs., Ltd.*, No. 2010-1001, 601 F.3d 1359, 1366 (Fed. Cir. 2010) ("[T]he terms

of the counterclaim provision do not authorize an order compelling the patent holder to change its use code narrative"). As a result, Novo Nordisk has continued to maintain a wrongful and anticompetitive use code narrative that prevents FDA from approving Caraco's section viii statement or ANDA.

97. Novo Nordisk's wrongful and anticompetitive use code narrative submission for Prandin may also prevent Caraco from disproving infringement in the patent infringement litigation because it has prevented FDA from approving Caraco's ANDA with appropriate labeling "carve outs" that would have, as a matter of law, deprived Caraco's generic repaglinide of any potential to directly or indirectly infringe claim 4 of the '358 patent.

B. Novo Nordisk's Scheme to Wrongfully Suppress Generic Competition with a Fraudulently Obtained Patent and Sham Litigation

1. Fraud on the PTO to Obtain the '358 Patent

98. The '358 patent issued from U.S. Patent Application No. 09/459,526 ("the '526 application"). On or about December 13, 1999, applicants Dr. Peter Muller and Dr. Lisbeth Hemingsen filed the '526 application with the United States Patent and Trademark Office ("PTO"). The application claimed, *inter alia*, a method of treating patients with NIDDM by administering a combination of repaglinide with another drug that was used to treat NIDDM, metformin. Dr. Muller subsequently became the only listed inventor and applicant because of amendments to the claimed subject matter during the prosecution of the '526 application. The '526 application was assigned to Novo Nordisk A/S and was prosecuted by attorneys at Novo Nordisk Inc.

99. Cognizant that it was well known prior art to treat diabetes patients with repaglinide or metformin alone, the Novo Nordisk applicants and attorneys recognized that a

combination therapy was *prima facie* obvious and not patentable absent unexpected results. Indeed, they specifically included language and data in the patent specification designed to establish unexpected results and to preempt an obviousness rejection:

> Surprisingly, it has been found that when repaglinide is administered together with metformin to NIDDM patients whose glycemic control is poor on metformin alone a significant improvement in the glycemic control is observed. More particularly, it has been found that there is a synergism between repaglinide and metformin.

'358 patent at column 3, lines 7-12.

100. The preemption strategy failed, however. Upon examination of the '526 application, the PTO Examiner predictably rejected the claims because the prior art showed that it would have been obvious to combine repaglinide and metformin to treat patients with NIDDM. For example, on October 19, 2000, the Examiner stated that the prior art "teaches combination therapy as a rational approach to the treatment of NIDDM comprising administering agents that have different mechanisms of action and different side-effect profiles."

101. Initially, the Novo Nordisk representatives sought to sway the examiner with attorney argument. But, despite Novo Nordisk's arguments in response to the rejection, the Examiner maintained the rejection of the claims in three more Office Actions. For example, in the April 16, 2002 Office Action, the Examiner did not find Novo Nordisk's arguments persuasive because "the prior ar[t] is replete with examples of combination therapy wherein side-effects are minimized, dosages are reduced and a more clinically beneficial outcome is observed as compared with monotherapy."

102. In response to these rejections, Novo Nordisk argued that the combination of repaglinide and metformin had synergistic effects that a skilled artisan would not have predicted.

In support of their contention, Novo Nordisk relied on results from a clinical trial labeled as Example 3 in the application ("Example 3"). Novo Nordisk also referred to the statement in the '526 application that "[s]urprisingly, it has been found that when repaglinide is administered together with metformin to NIDDM patients whose glycemic control is poor on metformin alone a significant improvement in the glycemic control is observed. More particularly, it has been found that there is a synergism between repaglinide and metformin."

103. Ultimately, because the Examiner maintained her rejection of the claims notwithstanding Example 3, Novo Nordisk resolved to submit a declaration from Dr. Jeppe Sturis, a Principal Scientist for Novo Nordisk A/S, to establish the purportedly unexpected synergy exhibited by repaglinide and metformin in the treatment of diabetic patients. In doing so, Dr. Sturis necessarily assumed the same duty of candor to the PTO owed by the other individuals substantively involved in the prosecution. That duty of candor included a duty to fairly represent facts and argument and to disclose information that the PTO examiner would deem important in evaluating those facts and arguments. Anxious to obtain the '358 patent and extend the repaglinide monopoly, Novo Nordisk willfully breached their duties by affirmatively misrepresenting facts and by deliberately withholding evidence known to them that would have exposed their misrepresentations. Specifically, in the declaration, Dr. Sturis misrepresented the results from a rat study involving repaglinide and metformin, and he and/or others owing a duty of candor withheld the existence of studies inconsistent with the representations to the PTO.

104. Specifically, in his declaration to the PTO, Dr. Sturis described the results of a study in which he examined the effect of the combination of repaglinide and metformin on Zucker obese rats. Dr. Sturis concluded that his rat study, along with Example 3, "strongly

suggest[ed] that the combination of repaglinide and metformin has synergistic properties *in type 2 diabetic patients*." (Emphasis added.)

105. That assertion was false, intended to deceive, and material to the allowance of the claims of the '358 patent. Dr. Sturis did not attach the actual study report to his declaration. The report to Novo Nordisk makes it clear that, contrary to the characterization of his study in his declaration, the study did not support a finding that the rat study had any clinical relevance to the effect of the repaglinide-metformin combination in humans. In his report, which is an internal Novo Nordisk document *not* disclosed to the PTO, Dr. Sturis stated that "[i]n conclusion, we have demonstrated synergistic effects of repaglinide and metformin on glucose tolerance in the male Zucker rat. We *speculate* that the presence of greater than additive effects may be clinically relevant." (Emphasis added.)

106. Absent the false Sturis declaration, the '358 patent would not have issued. Indeed, the PTO examiner made this very point. After Novo Nordisk's submission of Dr. Sturis' declaration, on or about December 30, 2002, the Examiner allowed the claims directed to the combination of repaglinide and metformin "*[b]ased solely* on the Declaration submitted by Dr. Sturis and reconsideration of the synergistic effects demonstrated in Example 3." (Emphasis added.) In fact, Novo Nordisk conceded in the *Caraco* litigation that Example 3 and Dr. Sturis's declaration are the only scientific data submitted during the prosecution of the '526 application to support Novo Nordisk's contention that the combination of repaglinide and metformin has synergistic effects. Since the examiner rejected application multiple times when the only scientific support cited was Example 3, the statements in Dr. Sturis's declaration were obviously material.

2. Novo Nordisk's inequitable conduct before the PTO

107. Not only did Dr. Sturis misrepresent facts to the PTO in his declaration and fail to disclose the different conclusion he reached in his report, he (and/or others with a duty of candor) withheld highly material information that was inconsistent with both his declaration and the Example 3 data.

108. *First*, Novo Nordisk never disclosed to the PTO three clinical studies conducted by Novo Nordisk A/S that directly conflicted with Novo Nordisk's representation to the Examiner that "it has been found" that the combination of repaglinide and metformin had a synergistic effect:

a. On January 16, 2001, Novo A/S initiated a clinical study with a trial ID of AGEE-3010. The study assessed the effect on glycemic control before and after treatment with repaglinide or repaglinide and metformin combination therapy in patients with Type 2 diabetes. On or about December 2, 2002, Novo Nordisk A/S issued a final report for AGEE-3010. The final report states "[w]hen analyzed by repaglinide monotherapy and repaglinide and metformin combination therapy, *the synergistic effect of combination therapy observed by Moses et al. was not consistently seen in this trial*." (Emphasis added.) The Moses *et al*. publication referenced in this final report contained the same data and results as described in Example 3.

b. On or about July 25, 2002, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-3018. The study was conducted to compare the efficacy profile of repaglinide in combination with metformin as compared to metformin or repaglinide given as monotherapy for the treatment of Type 2 diabetes. On or about September 29, 2003, Novo Nordisk A/S issued a final report for AGEE-3018. The final report states "[t]he results observed

in this study were contrary to the study by Moses *et al*. which showed that HbA1c and FPG were significantly improved in the combination therapy of repaglinide/metformin compared to treatment with either drug as monotherapy in obese Type 2 diabetic subjects. *The synergistic effect of combination therapy observed by Moses et al. was not consistently seen in this trial* (only between combination and repaglinide for HbA1c)." (Emphasis added.)

c. On or about March 6, 2002, Novo Nordisk A/S initiated a clinical study with a trial ID of AGEE-1411. The study was conducted to compare the efficacy of metformin and repaglinide used in monotherapy with the combination therapy of metformin and repaglinide. On or about February 20, 2006, Novo Nordisk A/S issued a final report for AGEE-1411. The final report states that "[t]here was not a statistically significant difference among treatments for the change of HbA1c (%) in blood from baseline, neither for the intent to treat population, nor for per protocol population; that is, the three treatments [repaglinide monotherapy, metformin monotherapy, and the combination therapy of metformin and repaglinide] have the same effect over the patients, as the HbA1c was reduced in all treatments from visit 1 to visit 6."

109. These three clinical studies are all dated *before* the '358 patent issued on January 13, 2004, yet neither the existence nor the outcome of studies AGEE-3010, AGEE-3018, or AGEE-1411 was disclosed to the PTO during the prosecution of that patent.

110. Novo Nordisk's failure to disclose these three clinical studies to the Examiner constitutes a material omission and renders Dr. Sturis' inconsistent affirmative representations particularly material. Further, the results of these clinical trials conflict more generally with the representations made by Novo Nordisk A/S, Dr. Muller, and Dr. Sturis during the prosecution of

the ’358 patent that the combination of repaglinide and metformin had a synergistic effect when used to treat patients with NIDDM. These were the very representations that provided the *sole* basis for overcoming the Examiners’ repeated rejections of the application underlying the ’358 patent.

111. In fact, one of Novo Nordisk’s own documents confirms that these studies were material to the prosecution of the ’358 patent. In an email dated January 9, 2007, Novo Nordisk’s employees highlighted the importance of one of the studies, AGEE-3018, to the subject of a combination of repaglinide and metformin to treat patients with Type 2 diabetes. The email concerned the potential disclosure of AGEE-3018 to FDA as part of the NN4440 project. Project “NN4440” concerns or concerned the development of a fixed combination product of repaglinide and metformin. In this email, Cliff Hall stated (in underlined text), “this trial appears relevant, and I don’t see how we can avoid including it” in a production to FDA. There is no basis to believe that the study would be relevant to FDA’s consideration of the NN4440 project, but not relevant to the prosecution of the ’358 patent, which concerns the identical subject matter.

112. Upon information and belief, the existence and/or outcome of studies AGEE-3010, AGEE-3018, and AGEE-1411 were known to Novo Nordisk’s attorneys who prosecuted the ’358 patent, Dr. Muller and/or Dr. Sturis, and they intended, by withholding disclosure of these studies, to deceive the PTO.

113. *Second*, Novo Nordisk never disclosed to the PTO that one skilled in the art could not determine if a synergistic effect existed from the results of Example 3. One of the principal investigators of the study described in Example 3, Dr. Robert Moses, testified under oath that

this study was unable to determine if the combination of repaglinide and metformin had synergistic effects. Novo Nordisk and Dr. Sturis knew this to be the case because Dr. Richard Carr, a scientist at Novo Nordisk Inc., notified Dr. Sturis, among others, in a August 24, 2000 email that there was no "mathematical proof that synergy really exists" and that such data would be useful for patenting. Despite this knowledge, Novo Nordisk affirmatively represented to the Examiner that "*it has been found* that there is a synergism between repaglinide and metformin" based on the results from Example 3. (Emphasis added.) Novo Nordisk representatives with a duty of candor had no basis for such a representation. In fact, they knew it to be untrue.

114. *Finally*, as alleged above, Novo Nordisk representatives with a duty of candor never disclosed to the PTO that Dr. Sturis himself did *not* believe that his rat study had any clinical relevance to the effect of the repaglinide-metformin combination in humans, let alone showed synergism between repaglinide and metformin. Again, the report underlying that study – a report never disclosed to the PTO – merely said: "In conclusion, we have demonstrated synergistic effects of repaglinide and metformin on glucose tolerance in the male Zucker rat. We *speculate* that the presence of greater than additive effects *may* be clinically relevant." (Emphasis added.)

115. All of the above misrepresentations and omissions were material and were intended to (and did) deceive the PTO. Absent these material misrepresentations and omissions, the '358 patent would not have issued.

116. This is not the first instance in which Novo Nordisk has committed inequitable conduct. On a previous occasion, Novo Nordisk similarly misrepresented study results disclosed in a pharmaceutical patent application. In the August 3, 2004, decision entitled *Bio-Technology*

General Corp. v. Novo Nordisk A/S and Novo Nordisk Pharmaceuticals, Inc., No. Civ. 02-235-SLR, 2004 WL 1739722 (D. Del. Aug. 3, 2004), the District Court of Delaware held that Novo Nordisk committed inequitable conduct by failing to inform the patent examiner that the procedure described in their patent application was, in fact, never performed, and the procedure actually failed despite repeated attempts to perform it. This finding of inequitable conduct was affirmed by the Federal Circuit on October 5, 2005, in *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005).

3. Novo Nordisk's improper listing of the '358 Patent in the Orange Book

117. As described above, Novo Nordisk obtained the '358 patent by willful fraud on the PTO.

118. As the '358 patent was fraudulently obtained, it is unenforceable.

119. As a wrongfully obtained and unenforceable patent, the '358 patent was not eligible for listing in the FDA Orange Book at the time Novo Nordisk so listed it.

120. As Novo Nordisk knowingly listed an ineligible patent in the Orange Book, Novo Nordisk has deliberately and knowingly misused the FDA's Orange Book listing process in an effort to exclude A-rated generic competition to Prandin.

4. Novo Nordisk's filing of sham lawsuits

121. But for Novo Nordisk's unlawful listing of the '358 patent in the Orange Book, Caraco would have filed a Paragraph III certification with its ANDA for repaglinide, alleging that the only patent listed for the product, the compound patent, would expire March 14, 2009. Under the terms of the statute, a Paragraph III certification is not an act of infringement, and

Novo Nordisk would have had no basis upon which to sue. A-rated generic repaglinide would have been available as of March 15, 2009.

122. Instead, because of Novo Nordisk's fraud on the PTO and the consequent issuance of the '358 patent, Caraco had to make Paragraph IV certifications in its ANDA relative to the '358 patent, which ultimately resulted in the patent infringement litigation against it and its parent company (Sun Pharmaceutical Industries, Ltd.).

123. Novo Nordisk's patent infringement litigation against Caraco was a "sham." It was objectively baseless in that no reasonable litigant would expect success on its merits, and it was interposed solely to block generic repaglinide competition. It was objectively baseless because the '358 patent was fraudulently procured by Novo Nordisk.

124. In addition, Mylan Pharmaceuticals, Inc. ("Mylan") is a manufacturer of generic pharmaceutical products with its headquarters in Morgantown, West Virginia. In 2009, Mylan filed ANDA 90-252 with FDA for approval of generic repaglinide. Mylan's ANDA included a Paragraph IV certification that claims 1-3 and 5 of the '358 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's repaglinide. On April 7, 2009, Mylan provided notice of its Paragraph IV certification to Novo Nordisk.

125. On May 20, 2009, Novo Nordisk sued Mylan for infringement of the '358 patent. *Novo Nordisk Inc. et al v. Mylan Pharmaceuticals Inc.*, No. 3:09-cv-02445 (D.N.J.). Because Caraco was the first generic manufacturer to challenge the '358 patent, however, Mylan's ANDA may not be approved until after the expiration of Caraco's 180-day exclusivity period, if any. On March 31, 2010, the United States District Court for the District of New Jersey dismissed Novo Nordisk's infringement action against Mylan for failing to plead an act of

infringement in connection with Mylan's section viii statement, which was submitted in connection with claim 4 of the '358 patent.

126. By preventing Caraco (the first ANDA filer) from obtaining final FDA approval, Novo Nordisk may have created a "bottleneck" by which Mylan was also excluded from the relevant market. By statute, Mylan cannot come to market until 180 days after Caraco. Thus, the anticompetitive scheme has effectively kept out potential generic competitors for a drug that Novo Nordisk has conceded would be subject to immediate, rapid, and in most cases automatic, generic substitution.

127. As a result of Novo Nordisk's fraudulent procurement of the '358 patent and sham litigation based on that patent, generic competition to Prandin has been blocked and delayed, and Plaintiffs and the Class have overpaid for their purchases of repaglinide. But for the fraud and sham litigation, Caraco would have received final ANDA approval on March 15, 2009 (after the expiration of the compound patent) and would have immediately launched its generic repaglinide. Instead, Plaintiffs and the Class have been overcharged by paying more for their repaglinide requirements than they would have, as a direct and proximate result of Novo Nordisk's anticompetitive conduct.

128. In the alternative, as a result of Novo Nordisk's improper listing of the fraudulently-procured '358 patent in the Orange Book, the generic competitors would not have filed Paragraph IV certifications to the '358 patent, and Novo Nordisk would have no artificial act of infringement upon which to base its otherwise baseless patent litigation to enforce the patent. Generic competition to Prandin has been blocked and delayed thereby, and Plaintiffs and the Class have overpaid for their purchases of repaglinide. But for the improper Orange Book

listing of the ’358 patent, Caraco would have received final ANDA approval on March 15, 2009, (after the expiration of the compound patent) and would have immediately launched its generic repaglinide. Instead, Plaintiffs and the Class have been overcharged by paying more for their repaglinide requirements than they would have, as a direct and proximate result of Novo Nordisk’s anticompetitive conduct.

C. Overarching Scheme to Violate the Sherman Act

129. The anticompetitive conduct set forth separately above was also part of an overarching anticompetitive scheme by Novo Nordisk to unlawfully establish and maintain its monopoly in the market for Prandin (repaglinide) and exclude any actual or potential A-rated generic competitors.

130. Novo Nordisk’s overarching scheme consisted of the following conduct:

a. filing an improper use code related to the ’358 patent shortly before FDA approval of Caraco’s ANDA with appropriate labeling “carve outs” and this Court’s ruling on Caraco’s motion for summary judgment of noninfringement;

b. the fraudulent procurement of the ’358 patent from the PTO;

c. the improper listing of the ’358 patent in the FDA’s Orange Book; and

d. the filing of sham infringement litigation to enforce the fraudulently obtained ’358 patent.

131. Novo Nordisk’s overarching scheme to monopolize the market for repaglinide has worked. Novo Nordisk remains, to this day, the only supplier of repaglinide in the United States, and those who purchase directly from Novo Nordisk continue to suffer overcharges on these purchases, because an A-rated generic version of repaglinide is unavailable.

132. But for Novo Nordisk's overarching scheme to monopolize the market, generic entry would have occurred as early as March 15, 2009.

VIII. EFFECTS ON COMPETITION

133. The acts and practices of Defendants complained of herein had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Prandin from generic competition. Defendants' actions allowed Defendants to maintain a monopoly and exclude competition in the market for Prandin and its A-rated generic equivalents, to the detriment of Plaintiffs and all other members of the Class.

134. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Prandin without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing less expensive, A-rated generic versions of Prandin much sooner than they actually will be marketed.

135. The generic manufacturers seeking to sell generic repaglinide had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products.

136. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Prandin caused Plaintiffs and the Class to pay more than they would have paid for repaglinide products, absent Defendants' illegal conduct.

137. Generic versions of brand-name drugs typically are priced significantly below the price of their brand name counterparts, and typically capture a large percentage of the brand's sales, with the magnitude of both the price difference and the sales switch increasing over time

and as additional generic competitors enter the market. As a result, direct purchasers typically substitute generic versions of the drug for some or all of their purchases.

138. Generic entry and competition enables all direct purchasers of the drugs to: (a) purchase generic versions of a drug at a substantially lower price, and/or (b) purchase the brand-name drug at a reduced price. Consequently, brand-name drug manufacturers have a keen financial interest in delaying the onset of generic competition, and purchasers experience substantial cost inflation from that delay.

139. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiffs, would have paid less for repaglinide by (a) substituting purchases of less-expensive A-rated generic repaglinide for their purchases of more-expensive branded Prandin, (b) receiving discounts on their remaining branded Prandin purchases, and (c) purchasing A-rated generic repaglinide at lower prices sooner.

140. Moreover, due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Prandin.

141. Thus, Defendants' unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. ANTITRUST IMPACT UPON PLAINTIFFS AND MEMBERS OF THE CLASS

142. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Prandin from Defendants. As a result of Defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their repaglinide purchases. If generic competitors had not been unlawfully prevented from earlier

entering the market and competing with Defendants, direct purchasers, such as Plaintiffs, would have paid less for repaglinide by (a) substituting purchases of less-expensive, generic repaglinide for their purchases of more-expensive branded Prandin, (b) receiving discounts and/or lower prices on their remaining branded Prandin purchases, and (c) purchasing generic repaglinide at lower prices sooner.

143. As a consequence, Plaintiffs and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount of such damages will be calculated after discovery and upon proof at trial.

X. MONOPOLY POWER AND MARKET DEFINITION

144. At all relevant times, Defendants had monopoly power over Prandin and its A-rated generic equivalents, because they had the power to maintain the price of Prandin at supracompetitive levels profitably, without losing substantial sales, in the absence of A-rated generic competition.

145. A small but significant, non-transitory price increase by Defendants of Prandin would not have caused a significant loss of sales to other products.

146. Prandin does not exhibit significant, positive cross-elasticity of demand, with respect to price, with any product other than A-rated generic versions of Prandin.

147. Because of, among other reasons, its safety and efficacy profile, Prandin is differentiated from all products other than A-rated generic versions of Prandin.

148. Defendants needed to control only Prandin and its A-rated generic equivalents, and no other products, in order to maintain the price of Prandin profitably at supracompetitive prices.

149. Defendants also sold Prandin at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

150. Defendants have had, and exercised, the power to exclude competition to Prandin.

151. Defendants at all relevant times enjoyed high barriers to entry with respect to Prandin.

152. To the extent that defining a relevant product market is necessary in this case, the relevant product market is repaglinide, composed of Prandin and its A-rated generic equivalents.

153. The relevant geographic market is the United States.

154. At all relevant times, Defendants held a 100% share in the relevant product market in the United States.

XI. CLAIMS FOR RELIEF

(Monopolization Under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2)

COUNT 1: Monopolization Based on Filing Baseless Use Code Change

155. Plaintiffs incorporate by reference the preceding allegations.

156. At all times relevant, Novo Nordisk possessed monopoly power in the market for repaglinide in the United States, which Novo Nordisk sold as branded Prandin.

157. In order to prevent generic competition and unlawfully maintain its monopoly in the market for repaglinide, Novo Nordisk improperly filed with FDA a baseless use code change for the ’358 patent, thereby preventing Caraco from receiving final ANDA approval and launching its generic repaglinide.

158. Novo Nordisk's conduct constituted unlawful acts of monopolization and otherwise enabled it to unlawfully maintain its monopoly in violation of Section 2 of the Sherman Act.

159. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class have paid, and continue to pay, artificially inflated prices for their repaglinide purchases.

160. Plaintiffs and members of the Class have been injured in their business or property by Novo Nordisk's antitrust violations. Their injury consists of paying higher prices for their repaglinide purchases than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, flows from that which makes Novo Nordisk's conduct unlawful, and Plaintiffs are proper entities to bring a case concerning this conduct.

COUNT 2: Monopolization Based on Fraudulent Procurement of Patent

161. Plaintiffs incorporate by reference the preceding allegations.

162. At all times relevant, Novo Nordisk possessed monopoly power in the market for repaglinide in the United States, which Novo Nordisk sold as branded Prandin.

163. In order to prevent generic competition and unlawfully maintain its monopoly in the market for repaglinide, Novo Nordisk engaged in the anticompetitive conduct described above that included:

a. the fraudulent procurement of the '358 patent from the PTO;

b. the improper listing of the '358 patent in the FDA's Orange Book;

c. the filing of infringement litigation to enforce the fraudulently obtained '358 patent; and

d. the pursuit of an overarching anticompetitive scheme that involved the conduct set forth above that was designed to, and did, delay the introduction of A-rated generic versions of Prandin into the market.

164. Novo Nordisk's conduct constituted unlawful acts of monopolization and otherwise enabled it to unlawfully maintain its monopoly in violation of Section 2 of the Sherman Act.

165. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class have paid, and continue to pay, artificially inflated prices for their repaglinide purchases.

166. Plaintiffs and members of the Class have been injured in their business or property by Novo Nordisk's antitrust violations. Their injury consists of paying higher prices for their repaglinide purchases than they would have paid in the absence of those violations. Such injury, called "overcharges," is of the type the antitrust laws were designed to prevent, flows from that which makes Novo Nordisk's conduct unlawful, and Plaintiffs are proper entities to bring a case concerning this conduct.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that:

A. the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure; and certify Plaintiffs as the representative of the Class;

B. Judgment be entered in favor of Plaintiffs and the Class and against Defendants, and each of them, jointly and severally, for damages representing the overcharges paid by Plaintiffs and the other members of the Class, trebled;

C. The Court award pre- and post-judgment interest;

D. The Court award costs of suit, including reasonable attorneys' fees; and

E. Plaintiffs and the Class be granted such other and further as the Court deems just and necessary.

XIII. JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury of all of the claims asserted in this Complaint.

Dated: August 30, 2010.

Respectfully submitted,

s/ Patrick E. Cafferty

Patrick E. Cafferty
Cafferty Faucher LLP
101 North Main Street, Suite 565
Ann Arbor, MI 48104
(734)769-2144
(734) 769-1207 (fax)
pcafferty@caffertyfaucher.com
Bar No. P35613
Liaison and Co-Lead Counsel for Plaintiffs

Thomas M. Sobol
David S. Nalven
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway
Cambridge, MA 02142
(617) 482-3700
(617) 482-3003 (fax)
tom@hbsslaw.com
davidn@hbsslaw.com

Eric L. Cramer
David F. Sorensen
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
(215) 875-3000
(215) 875-4604 (fax)
ecramer@bm.net
dsorensen@bm.net

Co-Lead Counsel for Plaintiffs

J. Douglas Richards
COHEN MILLSTEIN SELLERS
& TOLL PLLC
150 E. 52nd Street, 30th Floor
New York, NY 10022
(212) 838-7797
(212) 838-7745 (fax)
drichards@cohenmilstein.com

Peter Kohn
FARUQI & FARUQI, LLP
101 Greenwood Avenue, Suite 600
Jenkintown, PA 19046
(215) 277-5770
(215) 277-5771 (fax)
pkohn@faruqilaw.com

Barry S. Taus
Archana Tamoshunas
TAUS, CEBULASH & LANDAU, LLP
80 Maiden Lane, Suite 1204
New York, NY 10038
(212) 931-0704
btaus@tcllaw.com

Executive Committee for Plaintiffs (along with Co-Lead Counsel)

Russell Chorush
HEIM, PAYNE & CHORUSH, LLP
JP Morgan Chase Tower
600 Travis, Suite 6710
Houston, TX 77002
(713) 221-2004
(713) 221-2021 (fax)
rchorush@hpcllp.com

Patent Counsel for Plaintiffs

CERTIFCATE OF SERVICE

I hereby certify that on August 30, 2010, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to all counsel of record.

/s/ Patrick E. Cafferty

Patrick E. Cafferty
Cafferty Faucher LLP
101 North Main Street, Suite 565
Ann Arbor, MI 48104
Tel.: 734-769-2144
Fax: 734-769-1207
pcafferty@caffertyfaucher.com
Bar No. P35613